REMARKS/ARGUMENTS

Claims 1-30 are pending in the captioned application and stand rejected. Applicants have amended claims 1, 5, 9-12, 17 and 18. Applicants hereby also cancel claims 2-4, 7, 19-25 and 30. Applicants respectfully request reconsideration and allowance of the claims in view of the amendments and the following arguments.

Claims 5, 18 and 19 stand objected to for failing to indent each active verb step or component. Claim 4 has been objected to as well. In response, Applicants have amended claims 5, 18 and 19 and cancelled claim 4. Applicants request reconsideration and withdrawal of these claim objections.

Claims 1-5, 7, 9-12, 17, 20 and 25-30 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully disagree. However, in an effort to expedite prosecution, Applications hereby remove the language objected to by Examiner, rendering the rejections moot.

Claims 1-4, 17 and 23-30 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lihme et al. (6,498,235). Applicants respectfully disagree.

In an effort to expedite prosecution, the claims are amended. Specifically, Applicants have amended claims 1 and 17 to refer to a "first" chromatography resin, to make it clearer that the present invention relates to the capture of antibodies which is the conventional term used for the first chromatography step in a multistep process, and to include an additional step, i.e., "followed by one or more additional

chromatography steps". For support of the amendment, see the specification page 12, lines 7-14.

Applicants submit that Lihme et al., in the Examiner cited section (col. 7, lines 37-47), relates to optional means for recovery of immunoglobulin from the eluting solution once the immunoglobulin has been released from the solid phase matrix. Specifically, Lihme et al. mention that "some sort of concentrating procedure would be preferred e.g. ultra-filtration, freeze-drying or precipitation". Applicants submit that the skilled person would not understand the phrase "concentrating procedure" as referring to chromatographic separation, especially not considering the examples listed, from which it would be understood that "concentrating procedure" does not refer to separation methods.

Lihme et al. also states at the cited passage that the immunoglobulin solution may be purified further in a "further processing step of optional character". Lihme et al. does not suggest or indicate that such a "further processing step" could be chromatography. It is noted that there are numerous ways of further purification of an immunoglobulin from an eluting solution, which are readily available to the skilled person.

Thus, Lihme et al. does not teach or suggest a method as claimed, which includes one or more further chromatography steps after the first contacting step. Applicants submit that a skilled person would not read a further chromatographic separation step into the method of Lihme et al. Thus the anticipation rejection over Lihme et al. should now be withdrawn.

Claims 1-10, 16-18, 23-27 and 29-30 stand rejected under 35 U.S.C. §102(b) or (e) as anticipated by Belew et al (US 6,852,230). Applicants respectfully disagree.

Applicants first submit that claims 1 and 17 have been amended to include an additional step, i.e., "followed by one or more additional chromatography steps". The Examiner states that Belew et al. teach that there can be further purification steps, such as traditional ion-exchange chromatography. This would, in the Examiner's view, anticipate claims 4, 5 and 18. Therefore, presumably this would also anticipate the amended claims 1 and 17. The Examiner finds support for the anticipation rejection in Belew et al., col. 1, line 66 - col. 2, line 12, as well as col. 3, lines 10-27.

Applicants submit that the first cited section of Belew et al. (col. 1, line 66 - col. 2, line 12) is extremely vague, and basically states that desalting can be needed at various stages of a process. Similarly, the other cited passage (col. 3, lines10-27) suggests that the desalting procedure can be used prior to reverse phase chromatography or ion exchange. However, none of the sections cited in Belew et al. mention antibodies. Thus, in the passages where Belew et al. suggest using a multi-modal cation exchanger in a first chromatography step, a specific teaching cannot be found for antibodies.

Applicants note that IgG is used in the experimental part, but there it is only as a model protein. In this context, it is noted that the testing of antibody binding to novel chromatography resins is commonly carried out on a number of model proteins of different natures (size, charge etc), such as IgG, BSA and others. Thus, a mere use of IgG as a model protein in the testing of chromatography resins is in no way

regarded as evidence or even an indication that such resin would be useful as a first step in a multistep process. There is no disclosure or suggestion in the experimental section that suggests a further chromatography step should be added afterwards. Applicants submit that as such, there is no anticipation for the independent claims 1, 5, 17 and 18, or the claims depending on these claims.

The skilled person working with the purification of antibodies (as opposed to simply binding a model protein that happens to be an antibody) will have the knowledge of antibody processes and he/she will be prejudiced against even thinking of using anything but affinity chromatography (Protein A) in the first capture step. This is because a high selectivity for the antibody is commonly required in the capture step. Affinity chromatography and in particular Protein A is well known for its high selectivity, and consequently affinity chromatography has been regarded as the dominating chromatography resin for capture of antibodies. See second paragraph of the attached excerpt from Antibody Purification Handbook (Amersham Biosciences, 2003). Thus, the teachings from Belew et al. would be understood by the skilled person to refer to desalting prior to e.g. anion exchange either for capture of other proteins than antibodies; or alternatively as intermediate steps in a multistep antibody purification process wherein the capture is by affinity chromatography. A skilled person would NOT read Belew et al.'s teachings as suggesting that the disclosed small, organic multimodal ligand could be used to replace Protein A as capture agent in an industrial process for antibody purification. Therefore the 102(b) or (e) rejection of claims over Belew et al. should be withdrawn.

Claims 1-3, 23-25, 27 and 29-20 stand rejected under 35 U.S.C. §102(a) as being anticipated by Johansson et al. (J. Chromat. A, 1016, 35, 2003). Applicants respectfully disagree. However, as discussed above, claim 1 is now amended to include certain limitations not taught by any of the references (i.e., "followed by one or more additional chromatography steps"), thus rendering the rejections moot.

Claims 1-3, 23-25, 27 and 29-30 stand rejected under 35 U.S.C. §102(a)/(e) as being anticipated by Maloisel et al. (WO 03/024588). Applicants respectfully disagree. However, as discussed above, claim 1 is now amended to include certain limitations not taught by any of the references, thus rendering the rejections moot.

Claims 1, 5, 11, 13-15 and 28 stand rejected under 35 U.S.C. §103(a) as been obvious over Belew et al. in view of Priori et al. (5, 118, 796). Applicants respectfully disagree.

As discussed earlier, Applicants note that although IgG is used in the experimental part of Belew et al., it is only as a model protein. There is no disclosure or suggestion in the experimental section that suggests a further chromatography step should be added afterwards. A skilled person working with the purification of antibodies (as opposed to simply binding a model protein that happens to be an antibody) will have the knowledge of antibody processes and will be prejudiced against using anything but affinity chromatography (Protein A) as the first chromatography step. Applicants submit that protein A molecule is very different from a small, organic multimodal ligand. A skilled person would NOT read Belew et al.'s teachings as suggesting that the disclosed method could be used to replace

Protein A as capture agent in a real-world process for antibody purification. The combination of Belew et al. with Priori et al. would not cure the deficiency of Belew et al. Nor would the combination render the claims obvious.

Claims 19-25 and 30 stand rejected under 35 U.S.C. §103(a) over a number of references and combinations thereof. These rejections are however moot in view of the cancellation of the claims.

Applicants wish to thank the Examiner for pointing out the typographical error on Applicants' Form 1449. Applicants are filing herewith a new Form 1449 with the correct citation and also a new citation and request the Examiner kindly acknowledge receipt in the next Office action.

Applicants respectfully request reconsideration and allowance of claims 1, 5-6, 8-18, and 26-29.

Early and favorable consideration is respectfully requested.

Respectfully submitted,

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